REMARKS

Claims 60, 62 and 65-91 are pending in the present application.

Priority

The Office Action states that the present application is not entitled to receive the benefit of US Serial No. 09/204,254 (now U.S. Patent No. 6,369,039) because the claims allegedly fail to comply with the written description requirements of 35 U.S.C. 112. The Examiner basically states that the new claims do not include all of the products listed in the specification that are considered angiogenic agents and that the Applicant selected some polypeptides from the list and excluded other polypeptides in the present specification and the '039 specification. Applicants traverse this rejection.

There is support for each angiogenic agent recited in each dependent claim. For example, claim 71 recites that the angiogenic agent is acidic or basic fibroblast growth factor. Exact support for this angiogenic agent can be found in col. 5, line 66 of the '039 patent. Claim 72 recites that the angiogenic agent is vascular endothelial growth factor. Exact support for this angiogenic agent can be found in col. 5, line 66-67 of the '039 patent. Claim 73 recites that the angiogenic agent is platelet-derived growth factor. Exact support for this angiogenic agent can be found in col. 6, line 2 of the '039 patent. Claim 74 recites that the angiogenic agent is platelet-derived endothelial growth factor. Exact support for this angiogenic agent can be found in col. 6, line 1 of the '039 patent. Claim 75 recites that the angiogenic agent is epidermal growth factor. Exact support for this angiogenic agent can be found in col. 5, line 66-67 of the '039 patent. Claim 76 recites that the angiogenic agent is transforming factor α or β. Exact support for this angiogenic factor can be found in col. 5, line 67 to col. 6, line 1 of the '039 patent. It is unclear to Applicants how these claims do not satisfy the written description requirement if there is *ipsis verbis* support for these claims in the '039 specification.

The Examiner's application of case law to support these rejections is inapposite. In all the cases cited by the Examiner (*Lockwood v. American Airlines*, *Purdue Pharma L.P. v. Faulding*, *In re Ruschig*), the express disputed claim limitations were not specifically identified in the specifications. Specifically, in *Lockwood*, none of the intervening applications described an individual terminal containing a video disk player,

which was the claim limitation in dispute (See *Lockwood v. American Airlines*, 107 F.3d 1565, 1572 (Fed. Cir. 1997)). In *Purdue Pharma*, a specific claimed medication ratio was not described in the specification (See *Purdue Pharma L.P. v. Faulding*, 230 F.3d 1320, 1326 (Fed. Cir. 2000)). In *In re Ruschig*, the specific claimed compound was not identified by formula and there was only support for it as choices made between several variables involved (*See In re Ruschig*, 54 CCPA. 1551, 1553 (C.C.P.A. 1967)). In the present case, on the other hand, there is exact support in the specification for the recited angiogenic agents. As such, Applicants submit that there is adequate written description for the claims. The Examiner has pointed to no case law that supports the position that all angiogenic agents described in the specification need to be claimed in order to satisfy the written description requirements.

Rejection Under 35 U.S.C. 112

Claims 60, 62, and 65-91 stand rejected under 35 U.S.C. 112 for introducing new matter. As Applicants stated in their previous Response to Office Action, original claim 26 describes a first therapeutic agent that is a genetic material and a second therapeutic agent that is a non-genetic material. Original claim 33, which depended from claim 26 recited that both the first and second therapeutic agent cause the production of an angiogenic agent. Therefore, there is support for a first therapeutic agent that is an angiogenic agent and a second therapeutic agent that is a polynucleotide agent as recited in the present claims. Throughout the Office Action, the Examiner states that there is no specific disclosure in the specification of an angiogenic agent and a polynucleotide encoding an angiogenic agent. However, the Written Description Guidelines issued by the USPTO clearly state that "there is no *in haec verba* requirement" to satisfy the written description requirement and that newly added claim limitations can be supported through "express, implicit, or inherent disclosure." *See* Guidelines for the Examination of Patent Application Under 35 U.S.C. 112, para 1, "Written Description" Requirement (Fed. Reg. Vol. 66, No. 4 (January 5, 2001) (page 13). Therefore, Applicants submit that the present claims do not introduce new matter and are fully supported by the originally filed disclosure.

Rejection of Claim Under 35 U.S.C. 103

Claims 60, 62, 65, 67, 71, 72, 73, 75, 77-80, 82-84, 8, 87, 88, 90 and 91 stand rejected under 35 U.S.C. 103 as being allegedly rendered obvious by U.S. Patent No.5,879,713 to Roth in view of U.S. Patent No. 5,869,037 to Crystal. Applicants traverse this rejection.

Roth states that biologically active molecules can be incorporated into a polymeric material and include "proteins, nucleic acid molecules, carbohydrates, lipids, and combinations thereof." Roth then describes several examples of each. Roth never describes a nucleic acid encoding an angiogenic agent and an angiogenic agent, and more importantly, there is no motivation, suggestion or teaching of the desirability of this specific combination in Roth. Further, there is no motivation to combine the teaching of Crystal and Roth to produce a medical device containing a polymeric coating comprising an angiogenic agent and a nucleic acid encoding an angiogenic agent. Crystal is directed to the in vivo transfer of angiogenic agents to adipocytes to reduce adiposity, not insertable medical devices to reduce restenosis.

For at least these reason, Applicants submit that the present claims are not rendered obvious by Roth in view of Crystal and Applicants request withdrawal of this rejection.

Claims 60, 62, 65, 66, 80 and 81 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by Roth in view of Crystal and further in view of U.S. Patent No. 5,851,521 to Branellec ("Branellec"). As stated above, Roth and Crystal do not disclose the combination of an angiogenic agent and polynucleotide encoding an angiogenic agent. Branellec does not cure this deficiency. For at least this reason, Applicants submit that the combination of Roth, Crystal and Branellec do not render obvious claims 60, 62, 65, 66, 80 and 81 and Applicants request withdrawal of this rejection.

Claims 60, 62, 69, 70, 84, and 85 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by Roth in view of Crystal and further in view of U.S. Patent No. 5,833,651 to Donovan ("Donovan"). As stated above, Roth and Crystal do not disclose the combination of an angiogenic agent and a polynucleotide encoding an angiogenic agent. Donovan does not cure this deficiency. For at least this reason,

Applicants submit that the combination of Roth, Crystal and Donovan do not render obvious claims 60, 62, 69, 70, 84 and 85 and Applicants request withdrawal of this rejection.

Claims 60, 62, 74, 76 and 89 stand rejected under 35 U.S.C. 103(a) as being allegedly rendered obvious by Roth in view of Crystal and further in view of U.S. Patent No. 5,652,225 to Isner ("Isner"). As stated above, Roth and Crystal do not disclose the combination of an angiogenic agent and a polynucleotide encoding an angiogenic agent. Isner does not cure this deficiency. For at least this reason, Applicants submit that the combination of Roth, Crystal and Isner do not render obvious claims 60, 62, 74, and 89 and Applicants request withdrawal of this rejection.

CONCLUSION

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees required in connection with the filing of this response, are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

KENYON & KENYON LLP

Dated: 6-6-06

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